UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)(KMW)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' JOINT MOTION TO EXCLUDE OPINIONS OF JOHN QUICK

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I. INTRODUCTION

Plaintiffs' class certification current Good Manufacturing Practices ("cGMP") expert John Quick has more than forty years of experience working in the pharmaceutical industry, including at Baxter International, where he held the position of "Vice President of Quality and Regulatory matters associated with Baxter's drug manufacturing facilities." (Quick Decl., at ¶ 1.[1]) He also has been involved in inspections of, and cGMP compliance issues relating to, multiple domestic and overseas FDA-regulated manufacturing facilities including certain facilities of Defendants to this litigation. Defendants do not challenge Mr. Quick's qualifications.

Based on his extensive training and experience, Mr. Quick opines on class certification on the cGMP issues, which are common to all class members, and also provides an overview of the context for his opinions such as the FDA drug approval process, the purpose and nature of cGMP regulations, the role and function of quality oversight in the drug manufacturing process, the consequences of non-compliance with cGMPs, and the common record evidence suggesting Manufacturer Defendants did not comply with cGMPs or exercise the appropriate level of care in discharging their quality assurance obligations. Mr. Quick considered the same regulatory

[1] For administrative efficiency, Plaintiffs refer the Court to the Declaration of Mr. Quick that is attached to Plaintiffs' Motion for Class Certification filed November 10, 2021. (ECF 1748-4.)

background and facts that he or any reasonable manufacturer would consider in the ordinary course. Thus, Mr. Quick reliably applies an appropriate methodology to the (common) facts in this case.

Defendants purposely ignore the context and purpose of Mr. Quick's *class certification* declaration. Specifically, Mr. Quick's declaration offers the core opinion that Defendants' acts or omissions constitute compliance/non-compliance with cGMPs and, what these facts could mean under the regulatory regime (i.e., Defendants' drugs were adulterated and/or misbranded) present as common issues "that would have impacted all Valsartan product equally." (Quick Decl., at ¶ 1). This core opinion—what the facts pertinent to whether any Defendant complied with cGMP are, and their import—is not only unchallenged by Defendants' experts; it is also largely unchallenged in Defendants' *Daubert* Motion.

Because Defendants do not and simply cannot contest Mr. Quick's core conclusion regarding the common nature of the cGMP and regulatory questions, they set up a straw man to attack – on the merits.

First, they argue he renders ultimate legal or regulatory conclusions. Not so. Mr. Quick discusses an overview of examples of the *facts* as to each Defendant's cGMP compliance efforts. That he opines on what the consequences of non-compliance might be (e.g., adulteration) does not convert his proper opinions to improper 'ultimate issue' testimony. Moreover, in this case, it is a *fact* that the FDA

found that several of Defendants' valsartan drugs *were adulterated*. Mr. Quick's reliance on extant regulatory statements and findings is proper, and are exactly the types of "facts and data" an expert can and should rely on. Further, the Court can defer the issue of whether Mr. Quick is rendering a legal or regulatory conclusion as to the underlying examples of facts he summarized, and the import of that innocuous reliance, until merits reports are submitted.

Second, Defendants complain that Mr. Quick's merits analysis is incomplete, when – as Mr. Quick explicitly stated in his class certification Declaration – he did not submit (and was not required to submit at this class stage) a complete merits analysis of Defendants' cGMP violations. Rather, his opinions discuss "demonstrative, and not exhaustive" examples (Quick Decl., at ¶ 187), to support the core assertion regarding the *common* nature of the questions involved. (Mot., at 2 (stating that the Quick declaration is an "impermissible factual narrative based on a subset of documents").) Mr. Quick did not endeavor to develop ultimate opinions on the liability merits, instead noting examples of the extensive cGMP violations, focusing at this class certification stage primarily on what was found by the FDA. (Quick 1/27/22 Dep. Tr. at 168:6-21 ("I pulled out examples that I thought were representative…."); 191:21-22; 194:3-195:18; 215:2-15; 231:17-18 ("these are just examples that apply to the entire class"); 242:7-13; 252:10-16 (**Ex. 1**)); Quick 1/28/22 Dep. Tr. at 48:2-7; 69:3-17; 85:11-16 (**Ex. 2**).)

Over and over again, Mr. Quick made clear in his class certification Declaration and deposition testimony that this factual overview was provided as the context and foundation for his class certification opinion – and was not intended to be his full merits analysis and opinions.[2] Thus, the entire thrust of Defendants' motion to seek to strike merits opinions that were never intended to be final or fully comprehensive at the class certification stage is premature.

Third, for similar reasons, Defendants' nitpicks over which documents Mr. Quick did or did not review fall flat. Mr. Quick relied on a rich collection of defense documents and testimony, and regulatory standards and findings, to render his class certification opinions. Most if not all of these materials are the exact same as those relied on by Defendants' regulatory experts. Whether Defendants believe Mr. Quick should have looked at another document or not goes to weight, not admissibility.

Finally, Mr. Quick is not offering an "impermissible factual narrative." Court after court has held that it is well within the province of qualified experts to opine regarding the application of complex regulatory schemes to a set of facts. That is

[2] Plaintiffs have retained additional cGMP experts and expect to serve multiple cGMP liability reports in the merits phase. The fact that the Defendants chose to serve merits reports from their experts during the class certification expert report phase does not convert Mr. Quick's appropriately limited report on class certification into a final report on the merits. Should Defendants disagree they need only look to the position they took with regard to Plaintiffs' expert Stephen Hecht, Ph.D. when they deposed him during the general causation expert phase, deferring questioning of Dr. Hecht on the parts of his report addressing liability until the merits phase is reached.

particularly true in this case where future merits expert opinions will be in large part derivative of the FDA's own findings that Defendants' VCDs were adulterated.

For these reasons, Defendants' motion should be denied.

II. APPLICABLE LAW

A. *Daubert* Standard

"Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.,* 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted). Consistent with the "liberal thrust" of the federal rules of evidence, "Rule 702, which governs the admissibility of expert testimony, has a liberal policy of admissibility." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 739 (3d Cir. 1994) (first quotation); *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation and quotation marks omitted) (second quotation). "Rule 702 has three major requirements: (1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *Pineda v. Ford Motor Co.,* 520 F.3d 237, 244 (3d Cir. 2008).

III. ARGUMENT

A. Defendants Ignore the Core Opinion of Mr. Quick's Declaration – Namely, That Common Evidence Will Establish Defendants' Lack of Compliance With cGMPs

In support of class certification, Mr. Quick's core opinion set forth in his class certification declaration is as follows: the cGMP deficiencies (most of which were documented by the FDA) were "serious, systemic issues related to their overall corporate quality assurance operations" that impacted all of Defendants' VCDs "equally and in the same manner" as to all class members. (Quick Decl., at ¶¶ 101-02, 188, 191.) Stated otherwise, and as set forth in Plaintiffs' Motion for Class Certification, the facts one would assess as to Defendants' cGMP compliance *vel non*—such as defense manufacturing and quality oversight records, defense witness testimony, regulatory findings, etc.—are the exact same (i.e., common) facts were the class comprised of one member or thousands. Defendants do not challenge that opinion directly and nowhere assert that serious, systemic cGMP issues would *not* impact prescription drugs equally and in the same manner, and that the facts establishing same would be relied on by every single class member were they to bring individual suits.

B. Defendants Are Incorrect That Mr. Quick Opines on Ultimate Issues

1. Mr. Quick Does Not Offer Legal or "Regulatory" Conclusions

Mr. Quick does not offer ultimate legal or "regulatory" conclusions. (*See* Def. Br. At 14, 17.) Applying his substantial expertise to the facts, he concludes that "each Manufacturer Defendant was observed to have serious, systemic issues related to

their overall corporate quality assurance operations." (Quick Decl., at ¶ 188.) That the *fact* of these cGMP failures would constitute violations of state law, as well as adulteration or misbranding under federal (or analogous) state regulations does not transmogrify Mr. Quick's conclusions into ultimate conclusions. Further, Mr. Quick opines, correctly, that "[t]he FDA identified these corporate quality assurance practices and failings as contributing to the Manufacturer Defendants' Valsartan products becoming contaminated with NDMA and NDEA." (Quick Decl., at ¶ 189). Again, this is not an ultimate legal or regulatory conclusion, it is a *fact*. Moreover, the FDA identified in Warning Letters issued to the manufacturers various systemic cGMP failures as the reason for nitrosamine contamination, and further as the basis for the FDA's finding that several Defendants' VCDS were adulterated. For example, FDA told ZHP in its November 29, 2018 Warning Letter that it observed "significant deviations from [cGMP]" resulting in ZHP's valsartan being "adulterated within the meaning of … 21 U.S.C. § 351(a)(2)(B)." (**Ex 3** (FDA Nov. 29, 2018 ZHP Warning Ltr.).) The *fact* that the FDA actually found adulteration here, and that Mr. Quick references same, is exactly the type of facts an expert should rely on, and does not convert Mr. Quick's conclusions into net opinions. [3]

[3] For example, Mr. Quick is well-versed and qualified to interpret and explain FDA Warning Letters. Those Warning Letters in this case included FDA determinations that Defendants' VCDs were adulterated and further explained that it was due to significant cGMP failures that resulted in NDMA/NDEA contamination. It is well

2. *It is Premature for the Court to Address the Validity of Merits Opinions Not Yet Offered*

To the extent Defendants believe Mr. Quick might have offered a stray legal or ultimate opinion over the course of two days of deposition, there is no need for the Court to grapple with this now. Mr. Quick has not offered a merits opinion; he simply proffers a reliable, fact-based opinion about the common evidence concerning Defendants' cGMP compliance *vel non*. It is premature for the Court to rule on this merits-based *Daubert* attack that is inapplicable at this stage. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4165021, at *3 (N.D. Ohio Sept. 3, 2019) (stating that "the admissibility of a particular statement or opinion is dependent on the context in which it is offered and the foundation on which it is based").[4]

within Mr. Quick's expertise and not a legal opinion for Mr. Quick to explain to the jury what that language as used by the FDA actually means.

[4] The cases cited by Defendants all involved *merits* expert reports, and in each of them the courts found that the plaintiffs' regulatory experts offered reliable opinions, including the regulatory process and a manufacturer's conduct with regard to complying or not complying with regulations, but simply could not testify at trial about the legal conclusion of whether a product was misbranded or adulterated. *See, e.g.*, *Robinson v. Ethicon, Inc.*, No. 20-03760, 2022 WL 614919, at *5-6 (S.D. Tex. Mar. 2, 2022). Notably, in *Robinson*, the FDA never issued any findings as to the product at issue. Here, by contrast, it is a *fact* that the FDA found several Defendants' products and facilities adulterated.

C. Defendants' Repeated Mischaracterizations of Mr. Quick's Opinions Go To Weight, Not Admissibility

Defendants repeatedly misrepresent Mr. Quick's opinions and set up a straw man to attack. None of their examples got to admissibility under Rule 702.

For example, Defendants' Motion repeatedly and falsely claims that Mr. Quick states that "*any* cGMP [violation], regardless of the type or severity, renders *all* product … adulterated[.]" (Mot., at 9 (emphasis in original); *see also* Mot., at 11 (" … any cGMP, regardless of type or severity …"); Mot., at 13 ("It could not conceivably be that any deviation from a cGMP renders all product … adulterated[.]").) No matter how many times Defendants say it, that is simply not Mr. Quick's opinion; Defendants offer no citation from Mr. Quick's Declaration or deposition in making these repeatedly false assertions.[5]

To the contrary, Mr. Quick made abundantly clear that he is focused solely on "serious, systemic issues related to their overall corporate quality assurance operations" and his preliminary observations of the "nature of these deficiencies" were that they were "high level corporate QA failings[.]" (Quick Decl., at ¶¶ 188,

[5] Even if Mr. Quick was offering such an opinion now, there is ample evidence to support it. FDA policy is that serious, systemwide cGMP violations render all product from a certain facility adulterated. Whether a factfinder may find the facts in this case suggest systemwide cGMP failures rendering all product adulterated (again, something Mr. Quick does not affirmatively opine on at this stage), is a common question to be decided at a later stage, not now.

191.) As if Mr. Quick's Declaration was not clear enough, he also reinforced that his focus was on serious and systemic issues at his deposition:

> **Q.** How did you determine which examples you would review?
> **A.** Well, there is no specific determination. I went through all the defendants and I pulled out examples that I thought were representative of what I considered to be serious examples -- serious GMP situations.
> **Q.** And the ones that you pulled out are the ones that are listed in your report?
> **A.** They are.
> **Q.** Okay. And in the second part of that sentence it says that you went through that exercise: In order to determine whether these examples of noncompliance with CGMPs are the type that would impact and be common to every valsartan product purchased by the class members. What do you mean by that?
> **A.** Well, I mean, we were talking about GMP situations, not like somebody not wearing a hairnet. Okay? That would not be what I would be talking about here. These would be something that would apply to everything.

(Quick 1/27/22 Dep. Tr., at 168:12-169:8.) And in his report, Mr. Quick identifies, on a defendant-by-defendant basis, the facts suggesting the serious cGMP failures. (Quick Decl., ¶¶ 101-186).

The Court should reject Defendants' disingenuous efforts to rewrite Mr. Quick's Declaration to suit their *Daubert* attacks on him.

D. Defendants' Accusation That Mr. Quick Had No System for Collecting Documents Is False and Immaterial

Another theme of Defendants' *Daubert* attack on Mr. Quick is to simply pretend that he has submitted a merits expert report when the Court has not yet set a deadline for such reports. Mr. Quick repeatedly stated in his Declaration and

testimony that his focus was on illustrative examples of serious and systemic cGMP issues (largely identified by the FDA) that demonstrate his core opinion that such cGMP issues affect all product equally.

Defendants claim that Mr. Quick failed to collect and review every single document in the case, and that he lacked a methodology for his collection. (Mot., at 15-17.) This is inaccurate. Mr. Quick did have a methodology tailored to the specific purpose of his class certification Declaration; he reviewed and referenced documents indicative of serious, systemic and/or corporate level cGMP failures to be able to illustrate how such high-level failings would impact all valsartan product equally. Since this is not a merits expert report, Mr. Quick focused on examples of serious, systemic cGMP failures largely pulled from the FDA's own findings and relayed in official FDA Warning Letters informing the Defendants who received them that the FDA had observed "significant deviations from [CGMP]" resulting in Defendants' VCDs being "adulterated within the meaning of section 501(a)(2)(B) of the [FDCA], 21 U.S.C. § 351(a)(2)(B)." So uncontroversial and factually established are these observations that not a single one of Defendants' cGMP experts was willing to affirmatively opine that the defendant was in cGMP compliance; some outright

agreed with Mr. Quick's *preliminary* observations that the defendants were not in compliance.[6]

As for Defendants' contention that Mr. Quick failed to review documents, it again misses the point of the class certification Declaration. As Mr. Quick repeatedly testified, a more complete analysis will occur at the merits stage of the litigation when the Court orders the submission of merits reports. (*See, e.g.*, Quick 1/28/22 Dep. Tr., at 48:15-22; 69:3-17; 85:11-16; 141:15-142:1 ("My report only lists examples. So there may be other examples … which might be in a report later, a merits report or something beyond that.").)

Additionally, Defendants' entire line of attack about what documents Mr. Quick did or did not review is immaterial. The law of this Circuit is clear that such attacks go to weight, not admissibility. *See, e.g.*, *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 194-95 (D.N.J. 2020) (defense expert's "deliberate choice to not review [certain] articles identified by Plaintiffs[] does not render her opinion inadmissible").

[6] For example, ZHP's cGMP expert David Chesney (who prepared a report that failed to address class certification) also conceded violations of cGMPs in ZHP's risk assessment for the manufacturing process, and that this violation rendered all API manufactured with that process adulterated. He made this concession after being shown a series of documents that were addressed during 30(b)(6) depositions of ZHP witnesses that were unknown to him – thus he did not review key documents and deposition testimony, but unlike Mr. Quick he was providing his substantive opinions on liability rather than opinions on class certification.

E. Defendants' Protestations that that the Facts Are Not the Facts Can Be Addressed by the Court or a Jury at a Later Stage

Much of the rest of Defendants' attack on Mr. Quick has its foundation in Defendants' unhinged position that the clear and FDA-documented serious cGMP deficiencies did not occur. This is in the face of overwhelming evidence including but not limited to the FDA's own determinations and the extensive record in the Defendants' own documents. Regardless, this is not the stage for the Court to sort through the merits. The parties can present dueling merits reports when called upon to do so, and the Court or a jury can evaluate each in turn.

For example, Defendants characterize Mr. Quick as providing an inadmissible factual narrative and cite cases excluding expert testimony where the sole purpose was to provide "historical commentary[.]" The purpose of Mr. Quick's recitation is not simply historical commentary; rather, Mr. Quick lays out examples of Defendants' serious and systemic cGMP non-compliance for a reason. He uses those examples to illustrate how that type of cGMP failing (i.e., high level corporate QA failures) would impact all valsartan equally. Courts in this Circuit (and elsewhere) routinely hold that expert testimony summarizing the complex regulatory regime governing drug approval and manufacture is appropriate and helpful. *See, e.g.*, *In re Suboxone Antitrust Litig.*, MDL No. 2445, No. 16-5073, 2020 WL 6887885 (E.D. Pa. Nov. 20, 2020) ("Numerous courts have found that 'the testimony of regulatory

experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is helpful to a jury.'" (collecting cases)).

IV. CONCLUSION

For the foregoing reasons, the motion to preclude Mr. Quick's class certification opinions should be denied.

Dated: June 2, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2022, a true and correct redacted copy of the foregoing was filed and served via the Court's CM/ECF system, and an undredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch
David J. Stanoch